EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Zactran

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued/ amended on	Product Information affected[2]	Summary[3]
II/0045	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	17/02/2021	20/04/2021	SPC, Labelling and PL	The Agency accepted the variation to change the number of times that the cap could withstand multiple punctures from 'up to 60 times' to 'up to 50 times with a 16G needle and up to 80 times with a 18G needle'. Editorial changes in the product information and changes to align the product information with the QRD template were accepted as well.
IG/1337	C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure	10/02/2021	n/a		n/a
IG/1203	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	20/03/2020	20/04/2021	Annex II and PL	The Agency accepted the variation to change the name of the site responsible for batch release of the finished product. The address remains unchanged.
T/0043	Transfer of Marketing Authorisation	02/12/2019	19/12/2019	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Merial SAS' to 'Boehringer Ingelheim Vetmedica GmbH'.

[1] Notifications are issued for type I variations (unless part of a group including a type II variation or higher procedure or a worksharing application). Opinions are issued for all other procedures.
[2] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).
[3] Since October 2019 summary information is no longer published for variations that do not impact upon the product information

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II/0042/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.b.1.g - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Widening of the approved specs for starting mat./intermediates, which may have a significant effect on the quality of the AS and/or the FP B.I.b.1.g - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Widening of the approved specs for starting mat./intermediates, which may have a significant effect on the quality of the AS and/or the FP	05/12/2019	n/a		n/a
IG/1127/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) in the safety database and/or major contractual arrangements for the fulfilment of PhV obligations, and/or change of the site undergoing PhV activities C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the PhV system	10/07/2019	n/a		n/a
IB/0040	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	13/06/2019	n/a		-
II/0039/G	This was an application for a group of variations. B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.g - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Widening of the approved specs for starting mat./intermediates, which may have a significant effect on the quality of the AS and/or the FP	13/09/2018	n/a		-
IA/0038	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an	09/08/2018	n/a		n/a

	approved test procedure				
IA/0037	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	25/07/2018	n/a		-
II/0036	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	07/12/2017	12/01/2018	SPC and PL	The European Commission amended the decision granting the marketing authorisation to add a new therapeutic indication: Bordetella bronchiseptica - new pathogen for the approved indication: treatment of swine respiratory disease (SRD).
X/0034	Annex I_3. Other changes specific to veterinary medicinal products to be administered to food-producing animals: change or addition of target species	16/03/2017	15/05/2017	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new food-producing species (sheep) to treat infectious pododermatitis (foot rot) associated with virulent D. nodosus and F. necrophorum requiring systemic treatment.
IA/0035	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	22/12/2016	n/a		The Agency accepted a type IA variation to register minor changes in the manufacturing process of the active substance Gamithromycin, used in the manufacture of ZACTRAN (150 mg/ml, solution for injection for cattle and pigs).
IAIN/0033/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release B.II.e.6.a - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that affects the product information	26/04/2016	15/05/2017	SPC, Annex II and PL	The Agency accepted the group of variations relating to the address of the site responsible for manufacturing, batch release, primary packaging and quality control of the finished product and to change the closure system of the primary packaging.
IB/0032	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	08/04/2016	n/a		The Agency accepted the variation to add a new reagent, sodium chloride, in the manufacturing process of the active substace Gamithromycin.
IA/0031/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	23/03/2016	n/a		The Agency accepted the group of variations to introduce two minor changes to the manufacturing process of the active substance Gamithromycin.
X/0027	Annex I_3. Other changes specific to veterinary medicinal products to be administered to food-producing animals: change or addition of target species	10/12/2015	10/02/2016	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new target species, pigs, for the treatment of swine respiratory disease (SRD) associated with Actinobacillus pleuropneumoniae, Pasteurella multocida and Haemophilus parasuis. The route of administration is intramuscular for a single dose of 6 mg/kg bw, and the withdrawal period for pig meat and offal

					is 16 days.
IA/0030	B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size	25/09/2015	n/a		The Agency accepted the variation to register an increased batch size for the active substance.
IG/0592	C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure	04/09/2015	n/a		n/a
IB/0028	B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products	01/04/2015	n/a		The Agency accepted the variation to register an additional chlorobutyl rubber stopper for ZACTRAN 150 mg/ml solution for injection for cattle.
II/0026/G	This was an application for a group of variations. B.I.a.1.g - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the AS that is not supported by an ASMF and requires significant update to the relevant AS section in the dossier B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	09/10/2014	n/a		The Agency accepted the group of variations to introduce of a new manufacturer of the active substance with additional quality changes.
IB/0025/G	This was an application for a group of variations. B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	25/08/2014	n/a		The Agency accepted the group of variations to make changes to a starting material used to synthesize the active substance gamithromycin.
IA/0024/G	This was an application for a group of variations.	30/04/2014	n/a		The Agency accepted the group of variations to make minor

	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure				changes to the approved test procedures for the finished product and an excipient.
IA/0023	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	02/04/2014	n/a		The Agency accepted the variation to tighten the ML2PR impurity limit and to include this impurity in individual unspecified impurity.
IB/0022	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	18/02/2014	n/a		The Agency approved the variation to extend the re-test period of gamithromycin active substance, based on the real time stability data.
R/0021	Renewal of the marketing authorisation.	16/05/2013	15/07/2013	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for ZACTRAN.
IA/0020	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	19/12/2012	n/a		The Agency accepted the variation relating to changes in a test procedure.
IA/0019	B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	19/12/2012	n/a		The Agency accepted the variation for changes to in-process test in order to comply with guideline EMEA/CVMP/126/95-FINAL.
IA/0018	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	02/08/2012	n/a		The Agency accepted the variation relating to a new method, complying with the current Eur. Ph. monograph 2.5.12.
IB/0017/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the currently approved batch size	09/02/2012	n/a		The Agency accepted the group of variations to register a manufacturer for the last step of the manufacturing process.
II/0016	B.II.e.5.c - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, and biological/immunological multidose parenteral medicinal products	10/03/2011	12/04/2011	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new presentation (50 ml bottle)
IB/0015/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process	26/11/2010	26/11/2010		The Agency accepted the group of variations for a minor change in the manufacturing process at new proposed facility and the addition of an alternate site of the manufacture of gamithromycin API.

	of the AS B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer				
IB/0014	C.II.6 - Changes to the labelling or the package leaflet which are not connected with the SPC	16/04/2010	28/10/2010	Labelling	The Agency accepted the variation for a reduction in text on the label of the 250 ml trilingual vials.
IB/0013	1b-30-b Change (replacement, addition or deletion) in supplier of packaging components or devices	05/02/2010	05/02/2010		The Agency accepted the variation to register a new supplier for the ergonomic shaped 100 ml, 250 ml and 500 ml polypropylene bottles.
IB/0012	1B-36-a Change in shape or dimensions of the container or closure	05/02/2010	05/02/2010		The Agency accepted the variation to register an additional shape (ergonomic) of the 100 ml, 250 ml and 500 ml polypropylene bottles.
IB/0011	1B-14-b Change in manufacturer active substance or starting material-new manufacturer	23/12/2009	23/12/2009		The Agency accepted the variation to add a new manufacturer of a starting material used in the synthesis of gamithromycin.
IB/0010	1B-14-b Change in manufacturer active substance or starting material-new manufacturer	23/12/2009	23/12/2009		The Agency accepted the variation for the registration of a new manufacturer of a starting material used in the synthesis of gamithromycin.
II/0008	II - Other quality changes	16/09/2009	24/09/2009		The European Commission amended the decision granting the marketing authorisation to change the qualified person responsible for pharmacovigilance.
IA/0009	1A-13-a Change in test procedure for active substance or starting material-minor changes test procedure	24/08/2009	24/08/2009		The Agency accepted the variation for a change in the analytical method for the determination of residual solvents in the active substance (gamithromycin).
II/0003	II - Other quality changes	17/06/2009	20/07/2009	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add polypropylene vial as a new primary packaging material for the bottle of Zactran.
IA/0007	1A-09 Deletion of any manufacturing site where batch control takes place	29/05/2009	29/05/2009		The Agency accepted the variation to delete a manufacturing site (responsible for secondary packaging and labelling) for the finished product.
IA/0006	1A-09 Deletion of any manufacturing site where batch control takes place	29/05/2009	29/05/2009		The Agency accepted the variation to delete a manufacturing site (responsible for manufacturing and primary packaging) for the finished product.
IA/0005	1A-23-b Change in source of excipient or reagent from TSE risk to vegetable or synthetic material	29/05/2009	29/05/2009		The Agency accepted the variation for a change to reagent used in the finished product to avoid BSE/TSE risk.
II/0004	II - Other quality changes	16/04/2009	23/04/2009		The European Commission amended the decision granting the marketing authorisation to delete the test of particulate matter in the release specifications of the finished product.

IB/0002	1B-33 Minor change in the manufacture of the finished product	02/03/2009	02/03/2009		The Agency accepted the variation to register minor changes to the manufacture of the finished product in order to adapt the manufacturing process to the manufacturing equipment in the Merial manufacturing site, concerning the use of an additional sterile diluent in the procedure for the control of the sterility of the finished product.
IA/0001	1A-38-a Change in test procedure of finished product-Minor change to approved test procedure	14/08/2008	14/08/2008		The Agency accepted the variation to include the use of an additional sterile diluent in the procedure for the control of the sterility of the finished product.